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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,463	09/30/2003	Richard S. Dillon	0042-P02998US01	8503

110 7590 02/22/2006

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EXAMINER	
AGARWAL, MANUJ	

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/677,463	DILLON, RICHARD S.	
	Examiner	Art Unit	
	Manuj Agarwal	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1-2-04

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/415,232, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. A pilot control valve, a monitor, an adjustable control valve, a computerized EKG monitor, a pressure storage tank, a servomechanism, and an air outlet valve were not disclosed. Accordingly, claims 1-13,15 are not entitled to the benefit of the prior application.

Claim Objections

Claim 1 is objected to because of the following informalities: Part G states that the pressure sensor is operable connected with the plastic enclosure. A plastic enclosure was not previously claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not state that the adjustable valve control manually regulates the flow of compressed gas into the flexible enclosure. Rather, it is stated that the opening of the pilot control valve 38, which is regulated by the servomechanism, causes the opening of the adjustable control valve 30 (paragraph 23). Furthermore, it is said that the adjustable control valve is automatically adjusted by the servomechanism (paragraph 23).

Claim Rejections - 35 USC § 103

Claims 1-4,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dillon (US 4,343,303) in view of Cooper (US 5,000,164))

Regarding claims 1-3, Dillon discloses an apparatus and method for enhancing blood circulation in a patient's extremity comprising **A** a rigid enclosure 10 to enclose a patient's extremity comprising an opening; **B** a flexible enclosure 16 within the rigid enclosure that extends circumferentially around a patient's extremity; **C** a source of compressed gas that inflates the flexible enclosure (see abstract); **D** a pilot control valve

38 (see fig 1 for relative placement) operable in an open and closed position to permit or restrict the flow of gas (col. 2 lines 58-65); **E** a monitor 40 that comprises an electrocardiogram (EKG) device and detects a patient's arterial pulse and open the pilot valve in response (col. 3 line 67–col. 4 line 2); and **F** an adjustable control valve 30 that regulates the flow of gas (col. 4 lines 28-34,40-42).

Dillon lacks a **G** pressure sensor that measures the pressure in the flexible enclosure and adjusts the flow of compressed gas. Cooper discloses an external counterpulsation device as well. His device comprises a pressure sensor 41 mounted on the inner chamber of his inflated enclosure (col. 2 lines 64-66) that detect the degree of compression accomplished by the device. This data is interpreted during treatment for adjustment of the pressure caused by the device (col. 2 line 69-col. 3 line 4). Coopers device accomplishes the same objection as the claimed invention. Thus it would have been obvious to one of ordinary skill at the time the invention was made to provide the apparatus of Dillon with pressure sensors as taught by Cooper is order to provide a means for detecting and adjusting the pressure applied to a human's extremity.

Regarding claim 4, following the logic above, the pressure sensor must be coupled to air compressor in order to adjust the flow of compressed air.

Regarding claim 14, Dillon discloses a method for enhancing circulation in a patient's extremity comprising the steps of **A** placing the extremity in a flexible enclosure adapted to surround the extremity (col. 2 lines 25-38); **B** connecting a flexible enclosure to a source of compressed gas (col. 5 lines 1-5) being operable to inflate the flexible enclosure with gas to create an internal pressure in the flexible enclosure and apply external pressure to the patient's extremity (col. 2 lines 25-38); **C** monitoring a patient's arterial pulse (col. 4 lines 34-46); **D** inflating the enclosure with gas after the arrival of the arterial pulse (col. 4 line 24-col. 5 line 5); and **E** releasing the gas (col. 4, lines 47-58).

Dillon lacks the steps of measuring the internal pressure in the flexible enclosure and adjusting the flow of gas in response to the said pressure. See rejection of claim 1, part G.

Claims 5-11,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dillon (US 4,343,303) in view of Cooper as applied above, and in further view of Shah, et al. (2004/0260218).

Dillon in view of Cooper lacks a pressure storage tank. Shah, et al. discloses an apparatus and method for counterpulsation. He states that it is well known in the art to include a storage tank for compressed air for delivery to the inflated apparatus containing an appendage. Air from this pressure storage tank is delivered to apply compression to the appendage. It would have been obvious to one of ordinary skill at the time the invention was made to provide a pressure storage tank to the apparatus of Dillon in view of Cooper as taught by Shah, et al for it is conventional in the art. Furthermore, the pressure storage tank inherently must be placed between the source of compressed gas and the structure to which air is delivered.

Regarding claim 6, see rejection of claims 1,5. The pilot control valve constitutes a **C** valve assembly. The presence of the valve assembly inherently places the **E** pressure storage tank between the source of compressed gas and the valve assembly, for the valve assembly functions as a conduit to deliver the compressed gas to the apparatus that is to be inflated. Thus, it is inherent that the tank will have an inlet with the source of compressed gas and an outlet with the valve assembly.

Regarding claims 7,9 see rejection of claim 1-3, part E.

Regarding claim 8, see rejection of claim 1,5.

Regarding claim 10, the apparatus of Dillon includes a valve stem 26 extending from the adjustable control valve 30. Dillon discloses the claimed invention except for the control valve providing the manual regulation of the flow of compressed gas. Rather, Dillon's apparatus provides for the automatic opening and closing of the valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a manual control of the valve it accomplishes the same result and involves only routine skill in the art.

Regarding claim 11, see rejection of claim 1. It would have been obvious to couple the pressure sensor of Cooper with the adjustable control valve of Dillon in order to provide a method to regulate the flow of compressed air into the flexible member based on the feedback signal delivered from the pressure sensor.

Regarding claim 13, Dillon's apparatus comprises an air outlet valve 32.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dillon (US 4,343,303) in view of Cooper in view of Shah et al. as applied to claims 5-11,13 above and in further view of Shabty et al. (2005/0137507).

Regarding claim 12 the pressure sensor of Cooper transmits its reading to a control circuit 43 for processing (col. 3 lines 1-4). This controller has control parameters that controls constriction of the limb. Shabty discloses a counterpulsation device that comprises of a computer as a controlling. This computer communicates with a valve assembly to control the inflation/deflation of the inflated enclosure. When the appropriate signal is sent, the valves are opened and air is injected into the system and vice versa. Although a computer does not constitute a servomechanism, it performs an identical function and is thus deemed an appropriate substitute. There is not information in the specification that details why the servomechanism is critical to the invention at hand. The computer would also automatically adjust the flow of air that enters the inflatable enclosure. It would have been obvious to one of ordinary skill to provide the computer of Shabty et al to the apparatus of Dillon in view of Cooper in view of Shah et al. to provide the automatic control of the sequential inflation/deflation of the inflated enclosure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuj Agarwal whose telephone number is (571) 272-4368. The examiner can normally be reached on Mon to Fri 9:00 AM 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Manuj Agarwal
Patent Examiner

MA

Danton D. DeMille
Primary Examiner